



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 24, 2017

Ann M. Tillman
Agent for Promika, LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig harbor, WA 98332

Subject: Label Amendment – Updating Net Weights of collar and Directions for Use
Product Name: SALVO FLEA & TICK COLLAR FOR DOGS
EPA Registration Number: 91300-4
Application Date: 12-April-2017
Decision Number: 528894

Dear Ms. Tillman,

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 91300-4
Decision No. 528894

with FIFRA section 6. If you have any questions, you may contact Julie Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Sincerely,

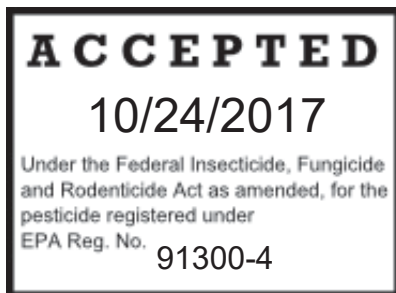
A handwritten signature in black ink, appearing to be 'Kable Bo Davis', enclosed within a hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

**Primary brand name: SALVO™ FLEA & TICK COLLAR FOR DOGS
[ABN: ShieldTec Flea & Tick Collar for Dogs]**

SALVO™ FLEA & TICK COLLAR FOR DOGS [ABN: ShieldTec Flea & Tick Collar for Dogs]



{Sublabel 1: SALVO™ FLEA & TICK COLLAR FOR DOGS [ABN: ShieldTec Flea & Tick Collar for Dogs]}

[text in [] denotes optional language or notes to reviewer]

{text in {} denotes location of text on packaging, notes to reviewer, text that will not be on final label}

(text in () appears on label)

{Front of Tin Container}

SALVO™ FLEA & TICK COLLAR FOR DOGS [ABN: ShieldTec Flea & Tick Collar for Dogs]

**For use on Dogs 12 weeks of age and older
One collar provides 6-month flea and tick protection
Two collars provide up to a total of 12-month flea and tick protection**

{When used, all three optional statements below will appear together on the same panel.}

[[Brand Name] [This product] contains deltamethrin, the active ingredient used in Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs].]

Scalibor® is a registered trademark of [Merck Animal Health] [Intervet International].

[Brand Name] is not manufactured or by distributed by [Merck Animal Health][Intervet International].

Salvo™ [Product Name] is a trademark of Promika, LLC.

{Optional Marketing Claims}

ACTIVE INGREDIENT:

Deltamethrin4.0%

OTHER INGREDIENTS 96.0%

Total.....100.0%

This product contains the toxic inert ingredient Bis(2-ethylhexyl) adipate (DEHA) at 18.0%

DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR CAUTION

See Label Booklet on back of Tin for Additional Precautionary Statements, Directions for Use and First Aid

Net Weight:

{Note to reviewer: for Injection molded Collars only:} [[Small/Medium][Two collars] 1.86 oz (52.6 g)[Two 0.93 oz. (26.3 g) Collars]]

[[Large/Extra Large] 2.31 oz (65.6 g) [Two 1.16 oz (32.8 g) Collars]]

{Note to reviewer: for Extruded Collars only; only one collar per tin: [One size fits all.][0.97 oz. (27.5 g) One 0.97 oz. (27.5 g) Collar]]

{Note to Reviewer: option for up to two collars per package} [One][Two] Collar[s]][Multi Packs] [[XX oz](XX g)]

{Booklet Label, Page 1: the part of label that is adhered to the back of the round tin container and is visible before accordion-style label is opened}

SALVO™ FLEA & TICK COLLAR FOR DOGS

[ABN: ShieldTec Flea & Tick Collar for Dogs]

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON [DOGS] [MEDIUM DOGS] [SMALL DOGS]
[SMALL BREEDS] [PUPPIES]
[DO NOT USE ON CATS]

[PRODUCT INFORMATION]

[[**Product Name**] [This collar kills fleas and ticks for up to [[6][six] months] [180 days].] Collar is a [double layer] sustained-release system [containing deltamethrin] combining the insecticidal actions of vapors and powders [working in [two] [three] ways to provide head to tail protection]. Thus, the collar has the effect of simultaneous usage of a spray and powder [in the control of fleas and ticks, including ticks that may carry Rocky Mountain spotted fever]. Use [**Product Name**] year-round for most effective control. [Replace every 6 months.]]

[Maximum effectiveness may not occur for 2-3 weeks after collar placement.] [If your dog is infested, you may consider shampooing your dog with an EPA registered [brand name] [flea and tick shampoo] to provide immediate relief from itching and biting before applying the [collar][product name]. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your dog will be killed. Collar will also kill ticks for up to [6 months] [180 days]. Collar will kill ticks including Brown dog tick (*Rhipicephalu sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*), which may carry the Lyme disease. This collar should be worn continuously.] [Reapply a new collar every [6] months.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not open protective [pouch][package] inside of the tin until ready to use. Do not let children play with this collar.

Do not use on puppies under 12 weeks. Do not use on cats. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing dogs. Sensitivities may occur after using ANY pesticide products for dogs. If signs of sensitivity occur, remove collar and bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide and is not to be taken internally by humans or animals.

Manufactured for:

Promika, LLC

501 Cascade Pointe Lane, Suite 102

Cary, NC 27513

[BAR CODE AREA]

EPA Reg. No. 91300-4

EPA Est. No.

[Manufactured in USA]

[Manufactured in France]

DO NOT USE ON CATS



{Booklet label, Page 2: Accordion-style Booklet Label that is attached to the back of the round tin container}

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, you may contact SafetyCall at 1-844-685-9173, twenty-four (24) hours a day, seven (7) days a week.</p>	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not open until ready to use. [Dust [will][may] form on collar during storage. Do not get dust in mouth or eyes.]

Only one collar is to be worn by your dog at any one time.

{Booklet Label, Pages 3 and 4 (if 4th page needed): Accordion-style Booklet Label that is attached to the back of the round tin container}

[Option #1 for Extruded collars]

Place collar around dog's neck, adjust for fit, and buckle in place. The collar must be worn loosely to allow for growth of the dog and to permit the collar to move about the neck. Generally, a properly fitted collar is one that when fastened, will snugly slide over the dog's head. Leave 2 or 3 inches for extra adjustment. Cut off and dispose of excess length. Wash hands after [installing] [placing] collar on dog. Replace collar every [6][six] months.

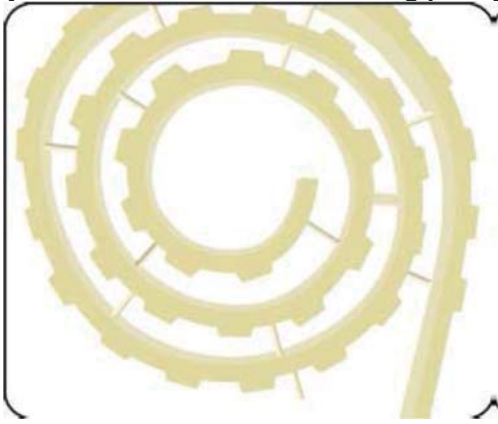
[Option #2 for Injection molded collars]

[Remove the collar from its packaging, separate the Peel-Away Comfort Strip and place in the trash.] Place collar around dog's neck and buckle in place [with the main clasp. Feed excess collar through the remaining two clasps for extra hold and a clean fit]. Adjust the collar for a snug fit to create contact between the collar and the dog's hair/coat for better product release and diffusion. A properly fitted collar will allow two fingers to be placed between the collar and dog's neck. The elasticity of the collar is designed to stretch in the event that the dog becomes entangled. Leave an excess of 1 – 2 notches (1/4 to 1/2 inch) past the last clasp. Adjust periodically for growing dogs. Cut off and dispose of excess length. Wash hands after [installing] [placing] collar on dog. Replace collar every [6][six] months.

[Option #3 for Injection molded collars]

[[1.] Do not open until ready to use. Dust [will] form on collar during storage. Do not get dust in mouth or eyes. Take the collar out of the packaging and stretch to full length. [The tabs that held the collar in place [should][will] fall off when stretching; pull on any remaining tabs to remove them.]

{Note to Reviewer: the following pictograms will appear only for Option #3 for Injection molded collars}



[[2.] Bend the buckle in half between the holes in the buckle, so that you can easily pass the end of the collar through both holes.]



[[3.] Place the collar around your dog's neck. Feed the collar through both holes [[ridges][notches] facing out]. Fit to the neck of the dog. Generally, a properly fitted collar is one that, when fastened, will snugly slide over dog's head and two fingers can be placed between the collar and dog's neck. Leave [2 or 3] [1 or 2] extra inches for collar adjustment, cut off remaining excess collar and dispose of in the trash.]



[4.] Wash hands after [installing] [placing] collar on dog. Replace collar every 6 months.]

[OPTIONAL IMAGES FOR DIRECTIONS FOR USE FOR INJECTION MOLDED COLLAR]

Proprietary Triple Clasp System



Peel-Away Comfort Strip



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide Disposal and Container Handling: Do not reuse container or used collar. Dispose of in trash.

[WARRANTY

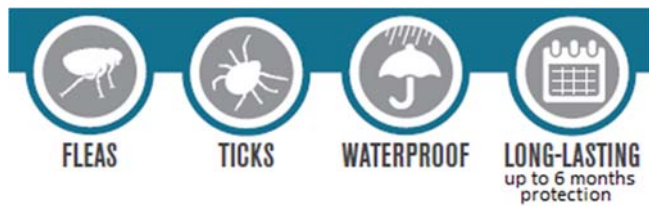
Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to be adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Promika, LLC is committed to providing high quality products. To the extent consistent with applicable law, Promika, LLC makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Promika, LLC, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[Satisfaction guaranteed. If you are not satisfied, we will make it right with a replacement or refund.]

[In Case of Emergency, call 1-844-685-9173]

{END - Booklet Label}

[Optional images:



{Optional Marketing Claims}

Fleas

1. [Kills Fleas [for up to 6 months]]
2. [Kills fleas that may cause anemia]
3. [Kills fleas that may cause bartonellosis]
4. [Kills fleas that may transmit tapeworms.]
5. [Kills [adult] fleas that may cause [Flea Allergy Dermatitis (FAD)][and][flea bite dermatitis]]
6. [Kills fleas and may reduce the incidence of FAD]
7. [Kills fleas that may cause anaplasmosis]
8. [Kills [adult] fleas which may cause flea bite anemia]
9. [Kills [adult] fleas which may transmit tapeworms]
10. [Kills Fleas for up to [6] [six] [months] [180 days] [!]]
11. [Kills fleas which may be a source of flea allergy dermatitis][(and) flea bite anemia][(and) tapeworm]
12. [Prevents new flea infestations]
13. [Kills adult fleas [before they lay eggs]]
14. [Flea [control][prevention] for dogs [& puppies]]
15. [Provides [long lasting 180 days] protection against fleas]
16. [Provides [long lasting 6 [six] month[s]] protection against fleas]

Ticks

1. [Kills Ticks[for up to 6 months]]
2. [Kills ticks for up to [6][six][months] [180 days][!]]
3. [Kills the Ticks that may carry Rocky Mountain Spotted Fever]
4. [Kills ticks that may cause babesiosis]
5. [Kills ticks for 6 months, including Deer ticks (vector of Lyme disease and anaplasmosis), American dog ticks (vector of Rocky Mountain spotted fever and ehrlichiosis), and Brown dog ticks (vector of ehrlichiosis, anaplasmosis, bartonellosis, canine hemoplasmosis, babesiosis)]
6. [Tick [control][prevention] for dogs [& puppies]]
7. [Kills ticks [including deer ticks which may carry Lyme disease]]
8. [Provides [long lasting 6 month] protection against ticks]
9. [Provides [long lasting 180 days] protection against ticks]

Multiple Pests

1. [Kills Fleas and Ticks [for up to [6 Months] [180 days]]]
2. [Provides [up to] [6] [six] [months] control [of fleas [and] [&] ticks]
3. [Kills Fleas [and] [&] Ticks]
4. [Kills Fleas and Ticks* for up to 6 months per collar][*including Brown dog tick, American dog tick & deer ticks which may carry the Lyme disease]

Multiple Package Claims

1. [[2][Two] Collars = a total of [12][twelve] month[s] protection]
2. [Up to a total of [12][twelve] month[s] protection [against ticks and fleas] with [2][Two] collars][in][1][one][per][package]
3. [12 Month Protection: apply 1 collar every 6 months]

Collar Fit Claims

1. [Lock and Stay Design]
2. [Click and Stay Design]
3. [Click to Fit Design]
4. [Fits Just Right [Design]]
5. [Comfort Fit [Design]]
6. [Designed for Comfort]
7. [Rugged][and][weatherproof]
8. [Time Release formula]
9. [Modern Click to Fit Design]
10. [Pull and Click]
11. [Best Fitting Flea Collar]
12. [Stay in Place design]
13. [Clicks into place]
14. [Won't slide and stretch]

15. [Won't be too loose or too tight]
16. [Won't be too loose or too tight [...fits just right (!)]]
17. [Fits just right [Design]]
18. [Fits just right ... won't be too loose or too tight]
19. [Right Size Collar [Design]]
20. [[New] Lock and Fit Design]
21. [Slide [to] [and] Fit [Design]]
22. [Fits securely] [Stays in place]
23. [Fit] [-] [and] Stay [Design]]
24. [Slide Fit [and] Stay Design]
25. [Right Fit [Design]]
26. [Right fit [Design]]
27. [Just Right Fit [Design]]
28. {For Extruded collars the following claims will be used}
[Fits All Size Dogs]
[Right Size Fit]
29. {For Injection molded collars the following claims will be used. These collars are offered separately for small/medium dogs and for Large/Extra-large dogs.}
[Small / Medium options: Fits Necks up to 20 inches]
[Large / X-Large: Fits Necks up to 25 inches]
30. [Great Fit]
31. [GRR...eat FIT]
32. [Grr.eat [Fit]]
33. [Adjustable]
34. [Cut to size]
35. [Size to fit]
36. [Fit to size]

All Other

1. [Long Lasting Protection for up to 6 months]
2. [Provides up to 6 months control of fleas and ticks]
3. [Continuous protection]
4. [For [Dogs], [Large Dogs], [Medium Dogs] [Small Dogs & Puppies] [Small Breeds]]
5. [[Features] insecticide-release technology]
6. [Wetting will not impair the collar's effectiveness or the dog's protection]
7. [Not affected by water] [Water resistant] [Waterproof]
8. [All Weather Collar]
9. [Convenient]
10. [Easy to [use][apply][attach]]
11. [Apply new collar every 6 months]
12. [For dogs [and puppies] 12 weeks of age and older]
13. [Pup-cessory]
14. [Fits right over existing dog collar]
15. [Proprietary Triple Clasp System]
16. [With Peel-Away Comfort Strip][Value Pack]
17. [Multi[-][Pack]
18. [Buy More and Save]
19. [Buy [X] Get [X] Free]
20. [Buy [X] and Save]
21. [Bonus Pack]
22. [For multiple dog [and puppy] households]
23. [Peel Here] [image of an arrow]
24. [Salvo® is a registered trademark of Promika, LLC]